

Title 16, California Code of Regulations
Article 5.5. Oral Conscious Sedation

Amend Sections 1044, 1044.1, 1044.2, 1044.3 and 1044.5 and add Section 1044.4

1044. Definitions

For purposes of this Article and of Articles 2.85 and 2.86 of Chapter 4, of Division 2 of the Code, the terms set forth below shall be defined as follows:

(a) "Outpatient basis" as used in Sections 1647.11 and 1647.19 means all settings where oral conscious sedation is being provided to dental patients with the exception of ~~means a patient under the age of 13 treated in a treatment facility which is not accredited by the Joint Commission on Health Care Organizations or licensed by an accrediting entity approved by the Medical Board of California pursuant to Chapter 1.3 of~~ Division 2 the California Department of Health Services as a "general acute care hospital" as defined in subdivision (a) of Section 1250 of the Health and Safety Code (commencing with section 1248).

~~(b) "Physical evaluation means recording patient age, weight, and general health, along with any known or suspected medically compromising conditions.~~

~~(e)~~ (b) A patient under oral conscious sedation shall be considered "sedated" for that period of time beginning with the administration of oral conscious sedation and continuing until that time when the dental procedures have been completed, and after the maximum effects of all agents have been experienced by the patient.

(c) "Age-appropriate" means under 13 years of age for the oral conscious sedation certificate for minor patients and 13 years or older for the oral conscious sedation certificate for adult patients.

Note: Authority cited: Section 1614, Business and Professions Code. Reference: 1647.10 and ~~1647.14~~ 1647.18, Business and Professions Code.

1044.1. Requirements, Standards

A dentist ~~shall~~ is not be required to possess an oral conscious sedation certificate if the oral conscious sedation administered to his or her ~~minor~~ patient is directly administered and monitored by a dentist who possesses a general anesthesia permit, a conscious sedation permit, or an oral conscious sedation certificate for a minor patient or is administered by a licensed physician and surgeon who possesses a general anesthesia permit. A dentist who only possesses an adult oral conscious sedation certificate may not provide oral conscious sedation to a minor patient. Notwithstanding the above However, the office in which the oral conscious sedation is administered shall meet the facilities and equipment standards set forth in Section 1044.5.

Note: Authority cited: Section 1614, Business and Professions Code. Reference: Section 1647.10, 1647.11, 1647.18 and 1647.19, Business and Professions Code.

1044.2. Board Approved Programs

(a) For purposes of Section 1647.12(a)(2)(b) and Section 1647.20(b), a post-doctoral program in periodontics, a general practice residency or other advanced education in a general dentistry post-doctoral program approved accredited by the Board Commission on Dental Accreditation that meets the didactic and clinical requirements of Section 1044.3 shall be deemed approved by the board. A dentist must submit evidence of completion of this requirement to the board.

Note: Authority cited: Section 1614, Business and Professions Code. Reference: 1647.10, ~~and~~ 1647.12, 1647.18 and 1647.20, Business and Professions Code.

1044.3. Board Approved Education

(a) The goal of an instructional program in oral medications and sedation is to provide the educational opportunity for dentists to receive training in the techniques and skills required to safely and effectively administer oral pharmacologic agents, alone or in combination with nitrous oxide-oxygen inhalation, for the purpose of obtaining conscious sedation in the minor or adult dental patient.

(b) The educational program shall be ~~in a facility~~ approved by the ~~B~~board and shall consist of satisfactory completion of at least 25 hours of instruction including a clinical component utilizing at least one age-appropriate ~~minor~~ patient. The course shall include but not be limited to, the following areas:

(1) Historical, philosophical, and legal aspects of age-appropriate oral conscious sedation of ~~minor~~ dental patients, including the Business and Professions Code.

(2) Indications and contraindications for the utilization of age-appropriate oral conscious sedation in ~~minor~~ dental patients.

(3) Patient evaluation and selection through a review of the medical history, physical assessment, and medical consultation.

(4) Definitions and characteristics for levels of sedation achieved with oral sedative agents, with special emphasis on the distinctions between conscious sedation, deep sedation, and general anesthesia as recognized by such organizations as the American Dental Association, the American Academy of Pediatric Dentistry and the ~~B~~board of Dental Examiners.

(5) Review of respiratory and circulatory physiology and related anatomy, with special emphasis on, and clinical experience in, establishing and maintaining an age-appropriate patent airway in the ~~minor~~ patient.

(6) Pharmacology of agents used in contemporary oral conscious sedation techniques including drug interactions, incompatibilities and side effects and adverse reactions.

(7) Indications, contraindications and technique considerations in the use of different contemporary age-appropriate oral conscious sedation modalities for ~~minor~~ dental patients.

(8) Patient monitoring during all stages of the procedure by clinical observation and appropriate mechanical devices for responsiveness, airway patency, and recording of vital signs.

(9) Importance of and techniques for maintaining proper documentation of the procedure, including aspects of informed consent, pre and post operative instructions, dietary considerations, preoperative health evaluation, rationale for the procedure, baseline and intermittent vital signs, a detailed record of all oral and inhalation drugs administered, the patient response to the drugs, and recovery and discharge criteria.

(10) Prevention, recognition and management of complications and life-threatening situations that may arise during age-appropriate oral conscious sedation of the ~~minor~~ dental patient, including the principles of ~~pediatric~~ advanced life support.

(c) A provider of a course in oral medications and sedation intending to meet the requirements of this section shall submit to the Board an application on form OCS-5 (Rev. 10/99), Application for Course Approval. The Board may approve or deny approval of any such course. Approval shall be granted after an evaluation of all components of the course has been performed and such evaluation indicates that the course meets the requirements of this section.

(d) Approval by the Board of a course in oral medications and sedation shall remain in effect for a period of twenty-four months, unless withdrawn sooner, after which a new application for approval must be submitted to the Board.

Note: Authority cited: Section 1614, Business and Professions Code. Reference: Sections 1647.10, ~~and~~ 1647.12, and 1647.20, Business and Professions Code.

1044.4. Documentation of 10 Cases.

(a) For the purposes of Section 1647.20(d), an applicant for an oral conscious sedation certificate for adult patients who has been using oral conscious sedation in connection with the treatment of adult patients shall submit the following documentation for each of the 10 cases of oral conscious sedation on form OCS-4 (Rev 1/06)

Documentation of Oral Conscious Sedation Cases.

(1) Patient's sex, age, and weight.

(2) Date of oral conscious sedation procedure.

(3) Type of dental procedure performed and duration of sedation.

(4) A description of the method, amount, and specific oral conscious sedation agent administered.

(5) A statement on how the patient was monitored and by whom.

(6) Patient's condition at discharge.

(b) Applicants shall also provide documentation or patient records,

including preoperative evaluation, medical history, monitoring of vital signs throughout the procedure, and condition at discharge for each patient.

(c) Applicants shall submit legible copies of the above required information with patient identifying information redacted.

Note: Authority cited: Section 1614, Business and Professions Code. Reference: Sections 1647.10, ~~and~~ 1647.12, 1647.20 and 1647.22, Business and Professions Code.

1044.5. Facility and Equipment Standards.

A facility in which oral conscious sedation is administered to ~~minor~~ patients pursuant to this article shall meet the standards set forth below.

(a) Facility and Equipment.

(1) An operatory large enough to adequately accommodate the patient and permit a team consisting of at least three individuals to freely move about the patient.

(2) A table or dental chair which permits the patient to be positioned so the attending team can maintain the airway, quickly alter patient position in an emergency, and provide a firm platform for the management of cardiopulmonary resuscitation.

(3) A lighting system which is adequate to permit evaluation of the patient's skin and mucosal color and a backup lighting system which is battery powered and of sufficient intensity to permit completion of any treatment which may be underway at the time of a general power failure.

(4) An appropriate functional suctioning device that permits aspiration of the oral and pharyngeal cavities. A backup suction device that can function at the time of general power failure must also be available.

(5) A positive-pressure oxygen delivery system capable of administering greater than 90% oxygen at a 10 liter/minute flow for at least sixty minutes (650 liter "E" cylinder), even in the event of a general power failure. All equipment must be age-appropriate and capable of accommodating ~~minor~~ patients of all ~~ages and~~ sizes.

(6) Inhalation sedation equipment, if used in conjunction with oral sedation, must have the capacity for delivering 100%, and never less than 25%, oxygen concentration at a flow rate appropriate for an age appropriate ~~minor~~ patient's size, and have a fail-safe system. The equipment must be maintained and checked for accuracy at least annually.

(b) Ancillary equipment, which must include the following, and be maintained in good operating condition:

(1) Age-appropriate ~~O~~Oral airways capable of accommodating ~~minor~~ patients of all ~~ages and~~ sizes.

(2) An age-appropriate sphygmomanometer with cuffs of appropriate size for ~~minor~~ patients of all ~~ages and~~ sizes.

(3) A precordial/pretracheal stethoscope.

(4) A pulse oximeter.

(c) The following records shall be maintained:

(1) An adequate medical history and physical evaluation, updated prior to each administration of oral conscious sedation. Such records shall include, but are not limited to, an assessment including at least visual examination of the airway, the age, sex, weight, ~~risk assessment~~ physical status (American Society of Anesthesiologists Classification), and rationale for sedation of the ~~minor~~ patient as well as written informed consent of the patient or, as appropriate, parent or legal guardian of the patient.

(2) Oral conscious sedation records shall include baseline vital signs. If obtaining baseline vital signs is prevented by the patient's physical resistance or emotional condition, the reason or reasons must be documented. The records shall also include intermittent quantitative monitoring and recording of oxygen saturation, heart and respiratory rates, blood pressure as appropriate for specific techniques, the name, dose and time of administration of all drugs administered including local and inhalation anesthetics, the length of the procedure, any complications of oral sedation, and a statement of the patient's condition at the time of discharge.

(d) An emergency cart or kit shall be available and readily accessible and shall include the necessary and appropriate drugs and age- and size-appropriate equipment to resuscitate a nonbreathing and unconscious ~~minor~~ patient and provide continuous support while the patient is transported to a medical facility. There must be documentation that all emergency equipment and drugs are checked and maintained on a prudent and regularly scheduled basis. Emergency drugs of the following types shall be available:

- (1) ~~Vasopressor~~ Epinephrine
- (2) ~~Corticosteroid~~
- (32) Bronchodilator
- (43) Appropriate drug antagonists
- (54) Antihistaminic
- (65) Anticholinergic
- (76) Anticonvulsant
- (87) Oxygen
- (98) Dextrose or other antihypoglycemic

NOTE: Authority cited: 1614, Business and Professions Code. Reference: 1647.10, ~~and~~ 1647.16, 1647.22 and 1647.24, Business and Professions Code.